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| 10/580,512 | 05/23/2006 | Yoshitaka Ichikawa | 8031-013-US | 2374 |

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| EXAMINER | |
|---|---|
| WHITE, EVERETT NMN | |

| ART UNIT | PAPER NUMBER |
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| 1623 | |

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/580,512 | ICHIKAWA ET AL. | |
| | Examiner | Art Unit | |
| | EVERETT WHITE | 1623 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-92* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-92* are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### *Election/Restrictions*

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 1-3, 8-11 and 22-46, drawn to a method of treating osteoarthritis with a derivative of glucosamine.

Group II, claims 1-3, 14, 15 and 22-46, drawn to a method of treating osteoarthritis with a derivative of galactosamine.

Group III, claims 1-3, 12, 13 and 22-46, drawn to a method of treating osteoarthritis with a derivative of cyclitol.

Group IV, claims 1-3, 16, 17 and 22-46, drawn to a method of treating osteoarthritis with a derivative of iminocyclitol.

Group V, claims 1, 2, 4, 8-11 and 22-46, drawn to a method of treating rheumatoid arthritis with a derivative of glucosamine.

Group VI, claims 1, 2, 4, 14, 15 and 22-46, drawn to a method of treating rheumatoid arthritis with a derivative of galactosamine.

Group VII, claims 1, 2, 4, 12, 13 and 22-46, drawn to a method of treating rheumatoid arthritis with a derivative of cyclitol.

Group VIII, claims 1, 2, 4, 16, 17 and 22-46, drawn to a method of treating rheumatoid arthritis with a derivative of iminocyclitol.

Group IX, claims 1, 2, 5, 8-11 and 22-46, drawn to a method of treating synovitis with a derivative of glucosamine.

Group X, claims 1, 2, 5, 14, 15 and 22-46, drawn to a method of treating synovitis with a derivative of galactosamine.

Group XI, claims 1, 2, 5, 12, 13 and 22-46, drawn to a method of treating synovitis with a derivative of cyclitol.

Group XII, claims 1, 2, 5, 16, 17 and 22-46, drawn to a method of treating synovitis with a derivative of iminocyclitol.

Group XIII, claims 1, 2, 6, 8-11 and 22-46, drawn to a method of treating subchondral bone edema with a derivative of glucosamine.

Group XIV, claims 1, 2, 6, 14, 15 and 22-46, drawn to a method of treating subchondral bone edema with a derivative of galactosamine.

Group XV, claims 1, 2, 6, 12, 13 and 22-46, drawn to a method of treating subchondral bone edema with a derivative of cyclitol.

Group XVI, claims 1, 2, 6, 16, 17 and 22-46, drawn to a method of treating subchondral bone edema with a derivative of iminocyclitol.

Group XVII, claims 1, 2, 7, 8-11 and 22-46, drawn to a method of treating cartilage degradation with a derivative of glucosamine.

Group XVIII, claims 1, 2, 7, 14, 15 and 22-46, drawn to a method of treating cartilage degradation with a derivative of galactosamine.

Group XIX, claims 1, 2, 7, 12, 13 and 22-46, drawn to a method of treating cartilage degradation with a derivative of cyclitol.

Group XX, claims 1, 2, 7, 16, 17 and 22-46, drawn to a method of treating cartilage degradation with a derivative of iminocyclitol.

Group XXII, claims 18, drawn to a method of treating osteoarthritis with the compound of formula I in Claim 18.

Group XXIII, claim 18, drawn to a method of treating rheumatoid arthritis with the compound of formula I in Claim 18.

Group XXIV, claim 18, drawn to a method of treating synovitis with the compound of formula I in Claim 18.

Group XXV, claim 18, drawn to a method of treating subchondral bone edema with the compound of formula I in Claim 18.

Group XXV, claim 18, drawn to a method of treating cartilage degradation with the compound of formula I in Claim 18.

Group XXVI, claim 19, drawn to a method of treating osteoarthritis with the compound of formula II in Claim 19.

Group XXVII, claim 19, drawn to a method of treating rheumatoid arthritis with the compound of formula II in Claim 19.

Group XXVIII, claim 19, drawn to a method of treating synovitis with the compound of formula II in Claim 19.

Group XXIX, claim 19, drawn to a method of treating subchondral bone edema with the compound of formula II in Claim 19.

Group XXX, claim 19, drawn to a method of treating cartilage degradation with the compound of formula II in Claim 19.

Group XXXI, claim 20, drawn to a method of treating osteoarthritis with the compound of formula III in Claim 20.

Group XXXII, claim 20, drawn to a method of treating rheumatoid arthritis with the compound of formula III in Claim 20.

Group XXXIII, claim 20, drawn to a method of treating synovitis with the compound of formula III in Claim 20.

Group XXXIV, claim 20, drawn to a method of treating subchondral bone edema with the compound of formula III in Claim 20.

Group XXXV, claim 20, drawn to a method of treating cartilage degradation with the compound of formula III in Claim 20.

Group XXXVI, claim 21, drawn to a method of treating osteoarthritis with the compound of formula IV in Claim 21.

Group XXXVII, claim 21, drawn to a method of treating rheumatoid arthritis with the compound of formula IV in Claim 21.

Group XXXVIII, claim 21, drawn to a method of treating synovitis with the compound of formula IV in Claim 21.

Group XXXIX, claim 21, drawn to a method of treating subchondral bone edema with the compound of formula IV in Claim 21.

Group XL, claim 21, drawn to a method of treating cartilage degradation with the compound of formula IV in Claim 21.

Group XLI, claims 47-57 and 68-92, drawn to a formulation comprising a derivative of glucosamine.

Group XLII, claims 47-53, 60, 61 and 68-92, drawn to a formulation comprising a derivative of galactosamine.

Group XLIII, claims 47-53, 58, 59 and 68-92, drawn to a formulation comprising a derivative of cyclitol.

Group XLIV, claims 47-53, 62, 63 and 68-92, drawn to a formulation comprising a derivative of iminocyclitol.

Group XLV, claim 64, drawn to a formulation comprising the compound of formula I in Claim 64.

Group XLVI, claim 65, drawn to a formulation comprising the compound of formula II in Claim 65.

Group XLVII, claim 66, drawn to a formulation comprising the compound of formula III in Claim 66.

Group XLVIII, claim 67, drawn to a formulation comprising the compound of formula IV in Claim 67.

2. The inventions listed as Groups I to XLVIII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: PCT Rule 13.2, requires that unity of invention exists only when the shared same or corresponding technical feature is a contribution over the prior art. The inventions listed as Groups **I to XLVIII** do not relate to a single general inventive concept because they lack the same or corresponding special technical feature. The "special technical feature" of Group I to XLVIII is **treatment of an oxteoarthritis related disorder in a mammal comprising administering to the mammal an aminosugar derivative** which is shown by **the Sherman et al patent (US Patent No. 6,117,851)** to lack novelty or inventive step **by disclosing treatment of osteoarthritis in a mammal by administering to the mammal an effective amount of poly-N-acetyl-D-glucosamine (see title and abstract of the Sherman et al patent)** and does not make a contribution over the prior art.

3. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the

requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

5. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during

prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

***Examiner's Telephone Number, Fax Number, and Other Information***

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Everett White whose telephone number is 571-272-0660. The examiner can normally be reached on 9:30 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Everett White/
Examiner, Art Unit 1623

/Shaojia Anna Jiang/
Supervisory Patent Examiner, Art Unit 1623